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09/536,736	03/28/2000	Helge Bastian	C12Q1/68	5490

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[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1636

/4

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/536,736**

Applicant(s)

*Bastian et al.*

Examiner  
**William Sandals**

Art Unit  
**1636**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Sep 16, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-22, 24-41, and 44-64 is/are pending in the application.

4a) Of the above, claim(s) 6-8, 56, and 57 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-5, 9-22, 24-41, 44-55, and 58-64 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on Sep 16, 2002 is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

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## DETAILED ACTION

### *Response to Amendment*

1. Paper No. 13, filed September 16, 2002 presented amendments to claims 1-5, 9, 13, 14, 16, 25-31, 38, 41, 44-49, 51, 54 and 55, and new claims 59-64, which have been entered. Claims 1-2, 24-41 and 44-64 are pending. Claims 6-8, 56 and 57 are drawn to a non-elected invention and are withdrawn from examination.
2. Amendments to the claims submitted in Paper No. 13 have overcome the rejections of the claims in the previous office action under 35 USC 112, second paragraph and the rejections are withdrawn.
3. Amendments to the claims submitted in Paper No. 13 have overcome the rejections of the claims in the previous office action under 35 USC 102 and the rejections are withdrawn.
4. Amendments to the claims submitted in Paper No. 13 have overcome the rejections of the claims in the previous office action under 35 USC 103 and the rejections are withdrawn.
5. Amendments to the claims submitted in Paper No. 13 have overcome the objection to the claims in the previous office action and the objection is withdrawn.
6. Amendments to the specification submitted in Paper No. 13 have overcome the objection to the specification in the previous office action and the objection is withdrawn.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

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***Claim Objections***

8. Claim 41 is objected to because of the following informalities: Claim 41 as amended in Paper No. 13 has duplicated language of the claim at lines 4-5. Appropriate correction is required.

***Drawings***

9. The drawings as submitted on September 16, 2002 have been approved by the draftsman.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-5, 9-22, 24-41, 44-50 and 59-64 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 4 and 5 have been amended to recite that the surface is "non-silicious". No support for the exclusion of the species of "silicious" surfaces from the genus of claimed surfaces has been found in the instant originally filed claims or specification. No citation or argument has been provided in the

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amendment of Paper 13 to support the amendment of claims 1, 4 and 5 reciting a surface which is “non-silicious”. Therefore, the term “non-silicious” constitutes new matter.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-5, 9-15, 18-21, 24-26, 28-32, 36, 39-41, 50-52, 55, 58-60 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,234,824 (Mullis).

Mullis teaches at the abstract, the summary and example 6, a process for isolating nucleic acids comprising charging a non-silicious surface (filter) with nucleic acid from the top of the surface. The nucleic acid is immobilized (trapped) on the surface of the filter, and released (eluted) off of the surface of the filter on the same side (top side) of the filter. A vacuum (suction) may be used to pull the solution through the surface (filter). The nucleic acid may be washed with a buffer solution. The buffer may contain a metal ion (salt), a chaotropic agent (ammonium sulfate) or an alcohol. The filter is hydrophilic. The releasing solution may be water or a buffer solution which may contain a metal ion (salt), a chaotropic agent (ammonium sulfate) and an alcohol. The process may be done in a multiwell plate.

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***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-5, 9-15, 18-22, 24-32, 36, 39-41, 44-52, 55 and 58-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,234,823 (Mullis) in view of US 6,028,186 (Tasset et al.).

The claims are drawn to a process for isolating nucleic acids comprising charging a non-silicious surface with nucleic acid from the top of the surface. The nucleic acid is immobilized on the surface of the filter, and released off of the same side of the surface. A vacuum (suction) may be used to pull the solution through the surface. The nucleic acid may be washed with a buffer solution. The buffer may contain a metal ion (salt), a chaotropic agent (ammonium sulfate), phenol or an alcohol. The surface may be a membrane (filter) where the filter is hydrophilic. The releasing solution may be water or a buffer solution which may contain a metal ion (salt), a chaotropic agent (ammonium sulfate) and an alcohol. The process may be done in a multiwell plate.

Mullis teaches at the abstract, the summary and example 6, a process for isolating nucleic acids comprising charging a non-silicious surface (filter) with nucleic acid from the top of the surface. The nucleic acid is immobilized (trapped) on the surface of the filter, and released

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(eluted) off of the surface of the filter on the same side (top side) of the filter. A vacuum (suction) may be used to pull the solution through the surface (filter). The nucleic acid may be washed with a buffer solution. The buffer may contain a metal ion (salt), a chaotropic agent (ammonium sulfate) or an alcohol. The filter is hydrophilic. The releasing solution may be water or a buffer solution which may contain a metal ion (salt), a chaotropic agent (ammonium sulfate) and an alcohol. The process may be done in a multiwell plate.

The chaotropic agents recited in claims 27 and 45 are listed in the specification as being members (species) of a genus of chaotropic agents which are equivalent for the practice of the instant invention. The members of the genus are deemed equivalent, and each species of the genus is therefore equivalent to each of the other species of the genus. One species therefore makes the other species of the genus obvious one over the other.

Mullis did not teach that the process buffer may contain phenol or various chaotropic agents recited in claims 27 or 45 which may be in the immobilization buffer.

Tasset et al. teach at columns 19-20 the isolation of nucleic acids on a surface and the release of the nucleic acids from the surface where the immobilization buffer, wash buffer or elution buffer may contain urea (one of the instant claimed chaotropic agents) and phenol.

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Mullis with Tasset et al. because each of Mullis and Tasset et al. teach a process for isolating nucleic acids comprising charging a non-silicious surface with nucleic acid from the top of the surface where the nucleic acid is

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immobilized on the surface of the filter, and released off of the same side of the surface. The teachings of Tasset et al. make obvious the modification of the method by using an immobilization buffer, wash buffer or elution buffer which may contain urea (one of the instant claimed chaotropic agents) and phenol.

One of ordinary skill in the art would have been motivated to combine the teachings of Mullis with Tasset et al. because Tasset et al. teach the desirable and beneficial isolation procedure for nucleic acids to purify, isolate and enrich a sample containing nucleic acids in a method where the immobilization, wash or elution buffers may contain urea and phenol. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Mullis and Tasset et al.

16. Claims 1-5, 9-15, 18-22, 24-36, 39-41, 44-52, 55 and 58-63 rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis and Tasset et al. as applied to claims 1-5, 9-15, 18-22, 24-32, 36, 39-41, 44-52, 55 and 58-63 above, and further in view of WO 97/08547 (Su).

The claims are as described above and where the membrane may be hydrophobic (various types of hydrophobic membranes).

Mullis and Tasset et al. teach the invention as described above.

Mullis and Tasset et al. did not teach that the membrane may be hydrophobic (various types of hydrophobic membranes).

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Su teach at the summary at pages 3-7, example 1 and claims 29-37 the use of hydrophobic membranes, and hydrophobized membranes in a method of binding and releasing nucleic acid from the surface of a membranes with immobilization buffers, washing buffers and releasing buffers containing ionic metal salts, organic acid salts, or hydroxyl derivatives of aliphatic hydrocarbons (alcohols).

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Mullis, Tasset et al. and Su because each of Mullis, Tasset et al. and Su teach a process for isolating nucleic acids comprising charging a non-silicious surface with nucleic acid from the top of the surface where the nucleic acid is immobilized on the surface of the filter, and released off of the same side of the surface. The teachings of Su make obvious the modification of the method by using a hydrophobic or hydrophobized membrane.

One of ordinary skill in the art would have been motivated to combine the teachings of Mullis, Tasset et al. and Su because Su recite at page 2, the desirable and beneficial use of the hydrophobic surfaces to improve the immobilization and release of nucleic acids in a process for isolating nucleic acids comprising charging a non-silicious surface with nucleic acid from the top of the surface where the nucleic acid is immobilized on the surface of the filter, and released off of the same side of the surface. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Mullis, Tasset et al. and Su

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17. Claims 1-5, 9-15, 18-22, 24-41, 44-55 and 58-64 rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis, Tasset et al. and Su as applied to claims 1-5, 9-15, 18-22, 24-36, 39-41, 44-52, 55 and 58-63 above, and further in view of EP 587,951 (Raybuck et al.) and US 5,869,073 (Sawan et al.).

The claims are as described above and where the membrane may be hydrophobized nylon.

Mullis, Tasset et al. and Su teach the invention as described above.

Mullis, Tasset et al. and Su did not teach that the membrane may be hydrophobized nylon.

Raybuck et al. teach at page 5 and the claims, the use of hydrophobic nylon membranes, and hydrophobized membranes in a method of binding nucleic acid on the surface of the membranes with immobilization buffers and washing buffers.

Sawan et al. teach at column 7, lines 18-39 and column 9, lines 32-59 the use of hydrophilic and hydrophobic membranes and hydrophilized and hydrophobized membranes, which may be nylon, in the capture and release of nucleic acids from the surface of the membrane.

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Mullis, Tasset et al., Su, Raybuck et al. and Sawan et al. because each of Mullis, Tasset et al., Su, Raybuck et al. and Sawan et al. teach a process for isolating nucleic acids comprising charging a non-silicious surface with nucleic acid

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from the top of the surface where the nucleic acid is immobilized on the surface of the filter. The teachings of Raybuck et al. and Sawan et al. make obvious the modification of the method by using hydrophilic and hydrophobic membranes and hydrophilized and hydrophobized membranes, which may be nylon, in the capture (and release - Sawan et al.) of nucleic acids from the surface of the membrane.

One of ordinary skill in the art would have been motivated to combine the teachings of Mullis, Tasset et al., Su, Raybuck et al. and Sawan et al. because Sawan et al. teach that hydrophobic membranes are beneficial and useful in a method of capturing (and releasing - Sawan et al.) nucleic acid from the surface of a hydrophobic membrane or a hydrophobized membrane (IE. nylon). Raybuck et al. teach that a hydrophobic membrane (which may be nylon) may be used to improve the purification of the nucleic acid by increasing the hydrophobic bonding of the nucleic acid on the membrane. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Mullis, Tasset et al., Su, Raybuck et al. and Sawan et al.

18. Claims 1-5, 9-15, 18-22, 24-41, 44-55 and 58-64 rejected under 35 U.S.C. 103(a) as being unpatentable over Mullis, Tasset et al., Su, Raybuck et al. and Sawan et al. as applied to claims 1-5, 9-22, 24-41, 44-55 and 58-64 above, and further in view of US 5,728,531 (Yamada et al.).

The claims are as described above and where the buffer may contain citric acid.

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Mullis, Tasset et al., Su, Raybuck et al. and Sawan et al. teach the invention as described above.

Mullis, Tasset et al., Su, Raybuck et al. and Sawan et al. did not teach that the buffer may contain citric acid.

Yamada et al. teach at example 14, the use of membranes, in a method of binding nucleic acid on the surface of the membranes with immobilization buffers and washing buffers.

It would have been prima facie obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of Mullis, Tasset et al., Su, Raybuck et al., Sawan et al. and Yamada et al. because each of Mullis, Tasset et al., Su, Raybuck et al., Sawan et al. and Yamada et al. teach a process for isolating nucleic acids comprising charging a non-silicious surface with nucleic acid from the top of the surface where the nucleic acid is immobilized on the surface of the filter, using buffers for immobilization and washing. The teachings of Yamada et al. make obvious the modification of the method by using buffers which contain citric acid in the capture of nucleic acids on the surface of the membrane.

One of ordinary skill in the art would have been motivated to combine the teachings of Mullis, Tasset et al., Su, Raybuck et al., Sawan et al. and Yamada et al. because the citric acid buffer taught by Yamada et al. is desirable and beneficial to use in a method of binding nucleic acids to membranes and is a well known and obvious choice which is available to one of ordinary skill in the art for practicing the method. Further, a person of ordinary skill in the art would have

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had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Mullis, Tasset et al., Su, Raybuck et al., Sawan et al. and Yamada et al.

***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Certain papers related to this application are **welcomed** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or

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applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

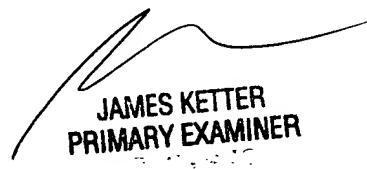
Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.

Examiner

January 26, 2003



JAMES KETTER  
PRIMARY EXAMINER  
JAN 26 2003